

**Amendment and Response**

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Applicant: Boldogh et al.

Serial No.: 10/691,330

Filed: October 22, 2003

Title: USE OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF AS  
INHIBITORS OF APOPTOSIS AND OTHER CELLULAR DAMAGE

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**Remarks**

The Office Action mailed April 18, 2005 has been received and reviewed. Claims 1, 5-7, and 12 having been amended and claim 24 having been cancelled, the pending claims are claims 1-23. Claims 16-23 being withdrawn from examination, as drawn to non-elected inventions, the claims currently under examination are claims 1-15. Reconsideration and withdrawal of the rejections are respectfully requested.

Support for claim amendments is found throughout the specification. For example, support for amended claims 1, 7, and 12 can be found, for example, at page 3, lines 8-9, 14-15, and 23-24 of the specification and in original claim 7.

**Restriction Requirement**

Applicants acknowledge the Examiner's reconsideration of the restriction requirement and thank the Examiner for the rejoinder and examination of SEQ ID NO:1-7 along with SEQ ID NO:8.

**Informalities**

The Examiner has requested clarification concerning the priority claim of the instant application. As stated in the first sentence of the application and on the application data sheet, the present application, filed October 22, 2003, claims priority under 35 U.S.C. §119(e) to U.S. Provisional Application Serial No. 60/420,369, filed October 22, 2002. While the Declaration, submitted November 3, 2004, also includes a priority claim to PCT US 03/33423, filed October 22, 2003, this priority claim is not included in first sentence of the application or on the application data sheet, and this application does not claim priority to PCT US 03/33423, filed October 22, 2003.

Page 12, line 19 of the specification has been amended to remove the recitation of a web site identified by a URL. Applicants respectfully submit that this objection to the disclosure is moot.

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In view of the above discussion, withdrawal of the objection to the disclosure is respectfully requested.

**Objection to the Claims**

Applicants respectfully submit that the Examiner's objection to claims 6 and 7, as reciting non-elected sequences, is moot in view of the amendment of claims 6 and 7.

**The 35 U.S.C. §112, First Paragraph, Rejection**

The Examiner rejected claims 1-5 and 7-15 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner asserted that while the specification is "enabling for a method of inhibiting apoptosis or inhibiting DNA damage in a cell, the method comprising contacting the cell with an effective amount of colostrinin, a constituent peptide with a defined sequence (e.g., SEQ ID NO:1-8), or a combination thereof," the specification does not reasonably provide enablement for such a method "comprising contacting the cell with an effective amount of colostrinin, a constituent peptide thereof, an active analog thereof, and combinations thereof, where the structure of the constituent peptide or the active analog is not defined, and the components of the combinations are not defined" (pages 3-4, Office Action mailed April 18, 2005).

This rejection is respectfully traversed. Applicants submit that as amended, the structure of the constituent peptides of colostrinin and the active analogs of a constituent peptide of colostrinin in claims 1-5 and 7-15 is adequately defined. Specifically, the constituent peptides of colostrinin are selected from the group consisting of SEQ ID NO:1-8 and the active analogs of a constituent peptide of colostrinin have "an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to a constituent peptide of colostrinin selected from the group consisting of" SEQ ID NO:1-8. Applicants submit that the

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specification provides adequate instruction to allow one of skill to make and use the claimed constituent peptides of colostrinin and active analogs of constituent peptides of colostrinin. Applicants have provided the amino acid sequences of the constituent peptides of colostrinin (SEQ ID NOs:1-8) (see, for example, page 10, lines 28-33 of the specification), as well as guidance for active analogs of constituent peptides of colostrinin having an amino acid sequences with at least about 15 percent proline (see, for example, page 12, lines 3-8 of the specification), and having at least about 70 percent structural similarity to one of constituent peptides SEQ ID NOs:1-8) (see, for example, page 12, lines 9-27 of the specification). Applicants maintain it is routine for one of skill in the art to make and use the claimed constituent colostrinin peptides and active analogs thereof using the specification for guidance.

Applicants respectfully submit that the specification provides adequate instruction to allow one of skill in the relevant art to make and use the invention commensurate with the scope of claims 1-5 and 7-15. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, are respectfully requested.

**The 35 U.S.C. §112, Second Paragraph, Rejection**

The Examiner rejected claims 1-15 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is respectfully traversed.

Specifically, the Examiner asserted that the recitation "combinations thereof" is indefinite, as "it is unclear what components and how much of each component are included in the combinations since the identities of the constituent peptides of colostrinin and their active analogs are not indicated in the claim" (pages 7-8 of Office Action mailed April 18, 2005). Applicants respectfully disagree and submit that the recitation "and combinations thereof" in claims 1, 7, 12 is not indefinite. Each claim utilizes traditional Markush group format; members "being selected from the group consisting of A, B and C." See MPEP § 2173.05(h). For example, claim 1 is drawn to "an apoptosis inhibitor selected from the group consisting of

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colostrinin, a constituent peptide of colostrinin, an active analog of a constituent peptide of colostrinin, and combinations thereof." The elements of the Markush group recited in claim 1 are colostrinin, constituent peptides of colostrinin, active analogs of constituent peptides of colostrinin, and each of the various combinations thereof. Applicants submit that the metes and bounds of the claim are clear to one of skill in the art and the recitation "combinations thereof" is not indefinite.

Further, the Examiner asserted that claims 1-15 are indefinite because the claims "lack an essential step in the method of inhibiting apoptosis or protecting against DNA damage in a cell. The missing step is the outcome of the treatment " (page 8 of Office Action mailed April 18, 2005). Applicants respectfully submit that this rejection is moot in view of the amendments of claims 1 and 7 (to recite "wherein the apoptosis inhibitor inhibits apoptosis in the cell"), and claim 12 (to recite "wherein the compound protects the cell against DNA damage").

In view of the above discussion, reconsideration and withdrawal of this rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

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**Summary**

It is respectfully submitted that the pending claims 1-23 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for  
**Boldogh et al.**

By  
Mueting, Raasch & Gebhardt, P.A.  
P.O. Box 581415  
Minneapolis, MN 55458-1415  
Phone: (612) 305-1220  
Facsimile: (612) 305-1228  
**Customer Number 26813**

July 18, 2005

Date

By: Nancy A. Johnson  
Nancy A. Johnson  
Reg. No. 47,266  
Direct Dial (612) 305-4723

**CERTIFICATE UNDER 37 C.F.R. 1.10:**

The undersigned hereby certifies that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated below and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Sara E. Wigan

Name: Sara E. Wigan

"Express Mail" mailing label number: EV 201892389 US

Date of Deposit: July 18, 2005